UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF NEW YORK

DENNIS RICHARD HARRISON,

Plaintiff,

-against-

1:06-cv-0932 (LEK/RFT)

MERCK & CO., INC.,

Defendant.

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

Pro se Plaintiff Dennis Richard Harrison ("Plaintiff") commenced this action on June 26, 2006, in New York Supreme Court, County of Ulster, alleging injuries caused by the prescription drug Vioxx. Dkt. No. 1-1 ("Complaint"). Defendant Merck & Co., Inc. ("Defendant") removed the action, which was then transferred to the Multi-District Litigation ("MDL") for Vioxx in the Eastern District of Louisiana. Dkt. Nos. 1; 6. The action was then remanded to the Northern District of New York after it was determined that Plaintiff's action raised issues that were unrelated to the other claims in the MDL. Dkt. No. 11.

Presently before the Court are Defendant's Motion for summary judgment and Plaintiff's Cross-Motion for summary judgment. Dkt. Nos. 29 ("Motion"); 30-2 ("Cross-Motion"). Also before the Court are Plaintiff's Second Motion for reconsideration and Plaintiff's Motion to compel Defendant to provide the Court with additional documents. Dkt. Nos. 38 ("Motion for Reconsideration"); 41 ("Motion to Compel"). For the following reasons, Defendant's Motion for summary judgment is granted, and Plaintiff's Cross-Motion for summary judgment, Second Motion for reconsideration, and Motion to compel are all denied.

II. BACKGROUND¹

Plaintiff alleges that Vioxx, a prescription drug produced by Defendant, caused a broken femur he suffered to heal improperly. Compl. ¶¶ 1, 26. Plaintiff is a resident of New York and Defendant is a corporation organized under the laws of the State of New Jersey. Id. ¶¶ 1, 2.

A. Plaintiff's Medical History

Plaintiff has a significant medical history. In his twenties, Plaintiff was diagnosed with ankylosing spondylitis, a degenerative form of inflammatory arthritis affecting the spine and major weight-bearing joints. Def. SMF ¶¶ 5-6. Plaintiff has had several surgeries in connection with that condition. Id. ¶¶ 8, 12, 13. Plaintiff has also suffered from a number of other long-standing conditions, including anemia. Id. ¶ 31. Several physicians have diagnosed Plaintiff with osteoporosis. See id. ¶ 29 (citing Dkt. No. 29-13 ("SSA Records") at 18, 21). Plaintiff disputes that diagnosis. Dkt. No. 29-28 ("Plaintiff Letter") at 2.

Due to his medical conditions, Plaintiff has taken numerous pain medications. Def. SMF ¶

25. Plaintiff took Vioxx uninterruptedly over a period beginning near its introduction to the market

¹ Both Defendant and Plaintiff have filed statements and opposing statements of material fact under Local Rule 56 of the District Court for the Eastern District of Louisiana, where the parties initially briefed their Motions. Dkt. Nos. 29-3 ("Defendant Statement of Material Facts"); 30-7 ("Plaintiff Opposition Statement"); 30-3 ("Plaintiff Statement of Material Facts"); 31-1 ("Defendant Opposition Statement"). The Court notes, however, that Plaintiff does not respond to Defendant's Statement of material facts with specific fact citations, but only makes conclusory denials. Pl. Opp'n. Furthermore, Plaintiff's own Statement of material facts bears minimal relevance to the elements of Plaintiff's claims. Pl. SMF. While the Court is mindful of Plaintiff's *pro se* status, since Plaintiff has not controverted Defendant's Statement of material facts with opposing facts, Defendant's Statement of material facts is deemed admitted insofar as it is supported with proper record citations, and forms the basis for the background herein provided. See Cross v. State Farm Ins. Co., 926 F. Supp. 2d 436, 441 (N.D.N.Y. 2013); see also GlobalRock Networks, Inc. v. MCI Commc'ns Servs., Inc., 943 F. Supp. 2d 320, 329 (N.D.N.Y. 2013) ("[T]he court must be satisfied that the citations to the record support the movant's assertions.").

in May 1999 until its withdrawal in September 2004. Compl. ¶ 43. At the time of his 2003 broken femur, Plaintiff was also taking ibuprofen, prednisone, Tylenol # 4, and Oxycontin for pain relief.

Def. SMF ¶ 27.

B. January 2003 Broken Femur

On January 9, 2003, Plaintiff slipped on ice and suffered a broken femur. Def. SMF ¶¶ 37-38. Plaintiff was admitted to Benedictine Hospital in Kingston, New York, and the following day, "had an open reduction and internal fixation of the right femur with a plate, screws and cerclage wires," performed by Dr. William Null. Id. ¶ 39. Plaintiff was discharged on January 13. Id. Plaintiff returned ten days later for re-evaluation and removal of his stitches. Id. ¶ 40. X-rays showed the fracture had "anatomic alignment, with excellent position and alignment of the cerclage wires, thigh plate, and screws." SSA Rds. at 38. At this appointment, Dr. Null noted that Plaintiff had been bearing weight on the leg, when it was supposed to be non-weightbearing. See Def. SMF ¶ 41.

Plaintiff next went for a follow-up on February 20, 2003. <u>Id.</u> ¶ 42. At this visit, x-rays showed that "two of the three cerclage wires" had torn and one proximal screw had "angulated about 20 degrees." <u>Id.</u> ¶ 43. Dr. Null's opinion was that Plaintiff had refractured his right femur and the fixation had failed due to trauma. <u>Id.</u> Dr. Null noted that Plaintiff had continued not to use crutches as instructed, and had suffered a fall down the stairs in his home. SSA Rds. at 39. Plaintiff later disputed that he fell down the stairs and claims that the Doctor misunderstood him, and that in fact only his crutches fell down the stairs. Dkt. No. 29-9 ("Plaintiff Deposition") at 219:6-12.

On February 25, 2003, Plaintiff was admitted to Albany Medical Center to undergo a revision surgery on his right femur. Def. SMF ¶ 44. When the incision was opened up, doctors

found pus and fluid, samples of which were later determined to contain enterococcus fecalis bacteria. See id. Dr. Paul Hospodar irrigated the wound, removed the broken hardware, and installed an anti-biotic spacer. See id. Plaintiff was put on a six-week course of intravenous antibiotic treatment, and on March 5, 2003, was discharged to a nursing home. Id. ¶ 45.

Over the next two months, Dr. Hospodar continued to monitor Plaintiff for signs of infection. Dkt. No. 29-15 ("Capital Orthopedic Records") at 15-16. X-rays taken on April 17, 2003, showed "some signs of healing of the fracture although minimal." Id. at 15. On May 16, 2003, Dr. Hospodar observed that Plaintiff appeared to have cleared his infection, and tentatively planned to schedule Plaintiff for a revision surgery in June. Id. at 16. A few days later, however, Plaintiff requested copies of his medical records from Dr. Hospodar in order to get a second opinion. See Def. SMF ¶ 48. After Plaintiff was "belligerent" to his staff, Dr. Hospodar limited Plaintiff's treatment to an as-needed basis on June 5, 2003, with the understanding that Plaintiff would transfer to another doctor. See id. ¶ 50; Cap. Ortho. Rds. at 17.

On June 23, 2003, Plaintiff was admitted to the Valley Hospital in New Jersey. Def. SMF ¶ 51. On June 27, 2003, Dr. Joseph Pizzuro performed surgery on Plaintiff, removing the anti-biotic spacer, and completing a revision of his right total hip replacement and a cemented proximal femoral replacement. Id. At follow-up appointments, it appeared that Plaintiff had recovered well. See id. ¶ 54.

C. Vioxx

Vioxx, a brand of the generic drug rofecoxib, is a non-steroidal anti-inflammatory drug ("NSAID") that operates by selectively inhibiting the Cox-2 enzyme. Compl. ¶¶ 47-48. Vioxx was approved by the Food and Drug Administration ("FDA") in May 1999. Id. ¶ 51. On September 30,

2004, Defendant pulled Vioxx from the market after a study conducted by an external drug safety monitoring board showed an increased risk of cardiovascular events among the Vioxx study group. Id. ¶ 66.

Plaintiff alleges that Vioxx causes inadequate bone repair. Compl. ¶ 64. Plaintiff cites to numerous animal studies stating that Vioxx and other Cox-2 inhibitors may interfere with bone growth and healing. See generally Compl., Exs. A, B. Defendant disputes that allegation, Mot. at 22, and argues that the only human study of the effect of Cox-2 inhibitors, including Vioxx, on non-union of bone following spinal surgery, concluded that there was no effect. Def. SMF ¶ 75.

Plaintiff's Complaint contains two causes of action. First, Plaintiff claims that Defendant was negligent in designing, manufacturing, and distributing Vioxx, when it had serious side effects, and that Defendant failed to warn of such side effects. Compl. ¶¶ 84-85. Plaintiff's second cause of action, framed as a fraud claim, further alleges that Defendant deceptively marketed Vioxx, presenting it as safe, without disclosing its true risks. Id. ¶¶ 88-98.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) instructs a court to grant summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Although "[f]actual disputes that are irrelevant or unnecessary" will not preclude summary judgment, "summary judgment will not lie if . . . the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); see also Taggart v. Time, Inc., 924 F.2d 43, 46 (2d Cir. 1991).

The party seeking summary judgment bears the burden of informing the court of the basis for the motion and of identifying those portions of the record that the moving party claims will

demonstrate the absence of a genuine issue of material fact. <u>Celotex Corp. v. Catrett</u>, 477 U.S. 317, 323 (1986). If the non-moving party will bear the burden of proof on a specific issue at trial, the moving party may satisfy its own initial burden by demonstrating the absence of evidence in support of an essential element of the non-moving party's claim. <u>Id.</u> If the moving party carries its initial burden, then the non-moving party bears the burden of demonstrating a genuine issue of material fact. <u>Id.</u> This requires the nonmoving party to do "more than simply show that there is some metaphysical doubt as to the material facts." <u>Matsushita Elec. Indus. Co. v. Zenith Corp.</u>, 475 U.S. 574, 586 (1986).

If the moving party will bear the burden of proof at trial, that party must support its motion with credible evidence that would entitle it to a directed verdict if not controverted at trial. Celotex, 477 U.S. at 331 (Brennan, J., concurring). Such an affirmative showing shifts the burden of production to the party opposing the motion, and requires that party either to produce evidentiary materials that demonstrate the existence of a genuine issue for trial or to submit an affidavit requesting additional time for discovery. Id.

A court must resolve all ambiguities and draw all reasonable inferences in favor of the nonmoving party. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000); Nora Beverages, Inc. v. Perrier Grp. of America, Inc., 164 F.3d 736, 742 (2d Cir. 1998). Where parties have filed cross-motions for summary judgment, "each party's motion must be examined on its own merits, and in each case all reasonable inferences must be drawn against the party whose motion is under consideration." Morales v. Quintel Entm't, Inc., 249 F.3d 115, 121 (2d Cir. 2001). A court's duty in reviewing a motion for summary judgment is "carefully limited" to finding genuine disputes of fact, "not to deciding them." Gallo v. Prudential Residential Servs., 22 F.3d 1219, 1224 (2d Cir.

1994).

IV. MOTION TO COMPEL

The Court first considers Plaintiff's Motion to compel Defendant to file certain documents from the MDL. Mot. Compel. Plaintiff identifies three classes of documents he believes should be on the docket: (1) documents designated according to Judicial Panel on Multidistrict Litigation Rule of Procedure 10.04(a) by Defendant for inclusion in the record on remand; (2) other documents that are relevant to the summary judgment briefing; and (3) documents which are not relevant to summary judgment but which may become relevant later. Dkt. Nos. 41-1; 41-2; 41-3. By Text Order dated June 27, 2014, the Court ordered Defendant to file "all papers regarding the pending summary judgment motions," and reserved Plaintiff's right to raise further discovery issues pending a decision on the dispositive motions. Dkt. No. 26. Defendant complied with this Order on July 9, 2014. Dkt. Nos. 29-31.

The Court has reviewed the documents listed by Plaintiff, purportedly relevant to summary judgment and not filed by Defendant. Dkt. Nos. 41-1; 41-2. Many of the documents cited by Plaintiff were in fact filed by Defendant. See, e.g., Dkt. No. 41-2 at 1 (citing Memorandum of law in support of Plaintiff's opposition to Defendant's summary judgment motion, filed by Defendant at Dkt. No. 30-6). Further, the other documents cited by Plaintiff are not relevant to deciding the summary judgment Motions. See, e.g., id. at 2 (citing motion filed with MDL for leave to file reply and order granting motion). Finally, because summary judgment is granted in favor of Defendant *infra*, the Court need not consider those documents which Plaintiff cites as irrelevant to summary judgment. See Dkt. No. 41-3. Plaintiff's Motion to compel is therefore denied.

V. MOTIONS FOR SUMMARY JUDGMENT

Defendant argues that summary judgment is appropriate for three reasons: (1) Plaintiff has failed to produce evidence that the healing of his femur fracture was prolonged; (2) there is no scientific evidence that Vioxx impedes bone healing in humans; and (3) Plaintiff's claims are time-barred by New York's statute of limitations. Mot. at 2. Defendant further argues that Plaintiff has not met his burden of proof because he has not designated an expert. Id. at 15 n.11.

Plaintiff, in turn, moves for summary judgment on all of his claims. Cross-Mot. Plaintiff's argues that Defendant has not offered evidence that Vioxx was safe, insofar as the study it relies upon was authored in part by Dr. Scott S. Reuben, who was found to have fabricated data and was disbarred by the FDA. <u>Id.</u> at 12. Plaintiff further argues that, in light of a settlement between Defendant and the United States Department of Justice, Defendant can no longer maintain as a defense that Vioxx was safe. <u>Id.</u> at 7.

A. Defendant Motion for Summary Judgment

1. Negligence

"To make out a prima facie case of negligence in New York [P]laintiff must show:"

(1) that the manufacturer owed him a duty to exercise reasonable care; (2) breach of that duty so that a product is rendered defective, i.e., reasonably certain to be dangerous; (3) that the defect was the proximate cause of [P]laintiff's injury; and (4) loss or damage.

Galletta v. Valmet, Inc., No. 04-CV-0313, 2007 WL 963288, at *3 (N.D.N.Y. Mar. 30, 2007) (citing McCarthy v. Olin Corp., 119 F.3d 148, 156 (2d Cir. 1997)). Defendant argues that Plaintiff has failed to meet his burden of proof with respect to both injury and causation. Mot.

a. Injury

The injury Plaintiff asserts is "inadequate" and prolonged bone repair. Compl. ¶ 26.

Specifically, Plaintiff claims that the hardware installed in the initial operation to repair his femur failed due to "inadequate bone healing." <u>Id.</u> ¶ 27. Plaintiff further claims that inadequate bone healing repeatedly delayed his revision operation. <u>Id.</u> ¶ 29. When the revision surgery was eventually performed, there was still insufficient bone growth, requiring the use of "massive amounts of glue" as a substitute. <u>Id.</u> ¶ 30. Plaintiff claims that what was expected to be a six-week recovery period, in fact lasted almost fourteen weeks as a result of inadequate bone healing. <u>Id.</u> ¶ 14.

Defendant argues that contemporaneous medical records belie Plaintiff's account of his recovery and that none of Plaintiff's "treating doctors viewed his healing process as inexplicably prolonged." Mot. at 17, 19. Defendant claims that the assertion that Plaintiff's healing was prolonged is entirely Plaintiff's own self-diagnosis. <u>Id.</u> at 18.

Defendant notes that at Plaintiff's first follow-up on January 23, 2003, x-rays showed that Plaintiff's femur appeared to be healing properly. <u>Id.</u> at 17. Defendant further notes that Dr. Null expressed concern that Plaintiff was bearing weight on his injured leg, when the leg was supposed to be non-weightbearing. <u>Id.</u> Dr. Null stated concern that the recovery would "fail" if Plaintiff continued to bear weight on the leg. SSA Rds. at 38. At the next follow-up, on February 20, 2003, Dr. Null recorded that Plaintiff had continued to use the crutches improperly and had slipped and fallen down the stairs when running to the door. <u>Id.</u> Following this incident, Plaintiff's leg was swollen, and x-rays showed that two of the three cerclage wires had been torn and one proximal screw angulated twenty degrees. Id. Dr. Null's impression was that Plaintiff had refractured his

² As noted *supra*, Plaintiff later denied that he had fallen down the stairs. Pl. Dep. at 219:6-12.

right femur and the fixture had failed from his fall down the stairs. <u>Id.</u> These records, Defendant argues, show that Plaintiff's femur had been healing normally, but was then refractured. Mot. at 18.

Defendant argues that further delays were caused by efforts to clear Plaintiff of an infection, which was discovered when Plaintiff went in for revision surgery on February 28, 2003. <u>Id.</u> at 18-19. Records from April 17, 2003, and May 16, 2003, show that Plaintiff's doctors were monitoring his infection, and had only come to believe by the latter date that the infection had subsided. Cap. Ortho. Rds. at 15-16. Finally, Defendant argues that Plaintiff's decision to switch his treatment from Dr. Hospodar in Albany to Dr. Pizzurro in New Jersey caused further delay to Plaintiff's recovery. Mot. at 19. Defendant contends that these other factors explain the length of Plaintiff's recovery, not inadequate bone healing.

Since Defendant has presented evidence that Plaintiff has failed to establish an injury—an essential element of Plaintiff's claim—Plaintiff must therefore demonstrate that there is a genuine issue of material fact in order to survive summary judgment. As noted *supra*, Plantiff has opposed Defendant's Statement of material facts only in a conclusory fashion and has not supported his response with citations to the record as required by Rule 56(c)(1)(A) of the Federal Rules of Civil Procedure. See generally Pl. Opp'n. Nor has Plaintiff otherwise produced evidence that would dispute the records cited by Defendant. Viewing the evidence in the light most favorable to Plaintiff, the Court finds that no reasonable juror could conclude that Plaintiff has suffered the injury alleged.

Though Plaintiff has not yet designated an expert and therefore does not have an expert

report,³ Plaintiff did submit a <u>Lone Pine</u> report signed by his rheumatalogist, Dr. James L. Wise. Pl. Letter. The <u>Lone Pine</u> report was prepared by Plaintiff and signed by Dr. Wise. <u>Id.</u> The report attests that a "reasonable degree of medical probability" exists that Vioxx caused the injury suffered by Plaintiff. <u>Id.</u> at 24. The report, however, does not express the opinion that Plaintiff actually suffered inadequate bone healing. Moreover, Dr. Wise did not treat Plaintiff for his femur fracture; any understanding that Dr. Wise had that Plaintiff's femur healed inadequately came from Plaintiff's own self-diagnosis. <u>See</u> Dkt. No. 29-27 at 48:17 to 50:1. Thus, Plaintiff's <u>Lone Pine</u> report does not support an inference that Plaintiff actually suffered inadequate bone healing.

The other evidence in the record is also insufficient to establish anything more than speculation that Plaintiff's femur healed inadequately. Certain treating doctors noted that signs of healing were "minimal." Cap. Ortho. Rds. at 15. However, no doctor attributed the rate of recovery to inadequate bone repair, nor noted that Plaintiff's recovery was unusually prolonged. The only evidence in the record from which one can conclude that Plaintiff suffered inadequate bone healing are Plaintiff's own self-diagnoses. In light of the evidence cited by Defendant and the inferences it creates, Plaintiff must show that there is a genuine issue of material fact that he suffered the injury alleged. Since Plaintiff has not shown that there is a genuine issue of material fact on an essential element of his claim, the Court must grant summary judgment in favor of Defendant on Plaintiff's negligence claim.⁴

³ Because the Court the Court grants summary judgment on other grounds, it need not reach Defendant's argument that summary judgment is appropriate because of Plaintiff's failure to designate an expert witness. Mot. at 15 n.11.

⁴ The Court does not address Defendant's argument that Plaintiff has failed to establish that Vioxx causes inadequate bone healing in humans. Mot. at 22-24.

2. Fraud

To establish fraud under New York law, a plaintiff "must prove a misrepresentation or material omission of a fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation or material omission, and injury." <u>Lama Holding Co. v. Smith Barney, Inc.</u>, 88 N.Y.2d 413, 421 (N.Y. 1996). As stated *supra*, Plaintiff has failed as a matter of law to establish injury. Thus, for the same reasons that Defendant is entitled to summary judgment on Plaintiff's negligence claim, summary judgment is also warranted in favor of Defendant on Plaintiff's fraud claim.⁵

B. Plaintiff Cross-Motion for Summary Judgment

Plaintiff argues that he is entitled to summary judgment on the ground that Defendant has not presented evidence that Vioxx is safe and has admitted in a settlement with the Department of Justice that it promoted Vioxx for unapproved uses. Cross-Mot. Since Plaintiff would bear the burden of proof at trial, he must support each element of his claim with evidence that would entitle him to a directed verdict if not controverted at trial. Celotex, 477 U.S. at 331 (Brennan, J., concurring). However, as the Court found *supra*, Plaintiff has not established that he suffered the injury alleged, which is an essential element of his claims. Plaintiff's Cross-Motion for summary judgment is therefore denied.⁶

⁵ Having found summary judgment warranted in favor of Defendant on all of Plaintiff's claims, the Court need not address Defendant's remaining argument that Plaintiff's claims were time-barred under the applicable the statute of limitations. Mot. at 24-28.

⁶ Plaintiff has also requested that the Court reconsider its July 30, 2014 Text Order denying Plaintiff's Motion for an extension of time to respond to Defendant's Motion for summary judgment. Mot. Recons. Plaintiff's Motion for reconsideration is denied. Plaintiff does not present

VI. CONCLUSION

Accordingly, it is hereby:

ORDERED, that Defendant's Motion (Dkt. No. 29) for summary judgment is **GRANTED**; and it is further

ORDERED, that Plaintiff's Cross-Motion (Dkt. No. 30-2) for summary judgment is **DENIED**; and it is further

ORDERED, that Plaintiff's Second Motion (Dkt. No. 38) for reconsideration is **DENIED**; and it is further

ORDERED, that Plaintiff's Motion (Dkt. No. 41) to compel is **DENIED**; and it is further **ORDERED**, that the Clerk of the Court serve a copy of this Memorandum-Decision and Order on all parties in accordance with the Local Rules.

IT IS SO ORDERED.

DATED: March 02, 2015 Albany, NY

Lawrence E. Kahn U.S. District Judge

new arguments demonstrating "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice," which would warrant reconsideration of the Court's Text Order. Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd., 956 F.2d 1245, 1255 (2d Cir. 1992). A motion to reconsider is not an opportunity "to relitigate an issue already decided." Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995).